

| <b>Notice of Allowability</b> | <b>Application No.</b>        | <b>Applicant(s)</b> |
|-------------------------------|-------------------------------|---------------------|
|                               | 09/160,076                    | SCOTT ET AL.        |
|                               | Examiner<br>Michael C. Wilson | Art Unit<br>1632    |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 7-19-04.
2.  The allowed claim(s) is/are 82-89.
3.  The drawings filed on 24 September 1998 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

**REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

Claims 1-81 have been cancelled. Claims 82-89 have been added and are allowable. Claim 82 is essentially equivalent to previous claim 70 with language adequate to overcome the 112/2<sup>nd</sup> issue in claim 70.

***Claim Rejections - 35 USC § 112***

The phrases "pharmaceutical composition," "that induces tolerance to an antigen," "suitable for introduction into an individual" and "wherein upon introduction to the individual said composition induces tolerance to the antigen in the individual" in claim 82 bear patentable weight under written description and enablement because each phrase must have at least one enabled use. In this case, the written description rejection and enablement rejections regarding using the composition as a pharmaceutical to induce tolerance to an antigen were withdrawn in the office action sent 8-28-03.

The rejection of claims 70, 72, 74, 80 and 81 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn because the claims have been canceled.

The term "autoimmune antigen" (previous claim 80) is not present in the new claims.

The term "allergen" (previous claim 81) is not present in the new claims.

***Claim Rejections - 35 USC § 102***

The phrase “pharmaceutical composition” in claim 82 does not bear patentable weight because the composition does not have to be used to treat disease.

The phrase “that induces tolerance to an antigen” in claim 82 does not bear patentable weight under art because it is an intended use and may not occur.

The phrase “suitable for introduction into an individual” in claim 82 does not bear patentable weight under art because it is an intended use and may not occur.

The phrase “wherein upon introduction to the individual said composition induces tolerance to the antigen in the individual” in claim 82 does bear patentable weight under art because it is a functional limitation of the composition.

The rejection of claims 69 and 79-81 under 35 U.S.C. 102(b) as being anticipated by McDonnell (Cell, 1989, Vol. 57, pg 79-88) has been withdrawn because the claims have been canceled.

The art at the time of filing did not teach or suggest a non-tumor hematopoietic cell or non-tumor lymphoid cell comprising a nucleic acid sequence encoding a fusion protein, wherein the nucleic acid sequence comprises a viral vector or portion thereof, said fusion protein comprising 1) an

immunoglobulin heavy chain or light chain; and 2) a polypeptide containing at least one epitope of an antigen. Specifically, one of skill would not have been motivated to replace the non-viral vector of McDonnell with a viral vector for the purpose of making a transgenic mouse.

***Double Patenting***

The objection to claim 81 under 37 CFR 1.75 as being a substantial duplicate of claim 69 has been withdrawn because the claims have been canceled. The new claims do not have duplicates.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants

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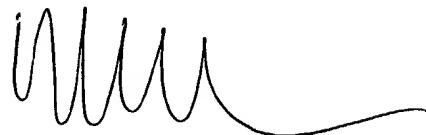
can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON  
PRIMARY EXAMINE